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| 09/784,980  | 02/16/2001  | Anthony John Bell    | 5641C1-07-LAV       | 5253             |
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| CHAWLA, JYOTI   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/784,980

**Applicant(s)**

BELL ET AL.

**Examiner**

JYOTI CHAWLA

**Art Unit**

1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6-9,28,30,31,33-36 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-9,28,30,31,33-36 and 55-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Applicant Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's submission of 1/31/2011 has been entered. Claims 10-27, 29 and 32 have been cancelled in current response and claims 58-59 have been added. Claims 1, 3 and 30 have been amended. Claims 1, 3, 4, 6-9, 28, 30-31, 33-36 and 55-59 are pending and examined in the present office action.

### ***Claim Objections***

Objection to claim 1 has been withdrawn based on applicant's amendment to the language of claim 1 to include word "of" in line 7.

Objection to claims 3 and 30 for depending on cancelled claims has been withdrawn based on applicant's amendments of 1/31/2011.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**1) Claims 1, 3-4, 6-9, 28, 30-31, 33-36 and 55-59 are rejected under 35 U.S.C. 103(a) as unpatentable over Carpenter (US 5637344), in view of the combination of Raymont (AU-A-71904/96), and Seang (WO 94/05260).**

**Note:** For the interpretation of transitional phrases "comprising" and "consisting essentially of" Examiner has relied on (MPEP 2111.03 [R-3] )

The transitional term "comprising", which is synonymous with "including," containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. (Emphasis added)

Transitional phrase "consisting essentially of" For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are,

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"consisting essentially of" will be construed as equivalent to comprising." (Emphasis added)

Regarding claims **1, 3, 28, 30, 55** Carpenter teaches a hard boiled candy composition comprising (or consists essentially of):

Regarding step (a) of independent claims **1, 28 and 55**, Carpenter teaches a confectionery base comprised of a mixture of at least one sugar (Carpenter, column 6, lines 20-28) and at least one carbohydrate bulking agent (Carpenter, column 6, lines 33-35) which is kept in an amorphous or glassy condition (Carpenter, column 2, lines 55-61), i.e., hard boiled candy.

Regarding step (b) of claims **1, 3, 28, 30, 55, and 58-59**, Carpenter discloses at least one botanical (e.g., cocoa powder, see Column 2, lines 65-67) having an unpleasant mouthfeel; however, Carpenter is silent as to the botanical being one from the list provided in amended claim 1, 28 and 55, i.e., botanical is selected from the group consisting of "Echinacea, Siberian Ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof". Regarding claims 1, 3, 28, 30, 55, Raymont teaches a lozenge composition (page 3, lines 30-31), i.e., a confection composition, which comprises at least one botanical, wherein the botanical may be Echinacea and Ginko Biloba (page 3, lines 19-20). Thus, confections including hard confections with botanicals, such as, Echinacea, were known in the art at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Carpenter and include botanicals such as, Echinacea or Ginko Biloba. One of ordinary skill would have been motivated to modify Carpenter at least for the purpose of deriving known benefits of botanicals, such as, Echinacea for the stimulation of immune system (see Raymont, page 5, lines 20-25) and Ginko Biloba for the stimulation of circulatory system (see Raymont, page 5, lines 20-25).

The limitation to the independent claims **1, 28 and 55** of "unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals" is

associated with botanicals "Echinacea, Siberian ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. John's wort, Valerian and Ephedra and combinations thereof", i.e., if any or a combination of above listed botanicals are present in a confection or food product, said botanicals will inherently contribute an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals to the confection or food product as claimed. It is noted that the newly added limitation of "having an unpleasant mouthfeel in the form of tingling sensation or astringency characteristic of said group of botanicals" (See e.g., lines 8-9 of claim 1, also part of independent claims 28 and 55) is inherent if any one of the claimed group of botanicals is present. Since, the Carpenter as modified above (rejection of step b) teaches Echinacea and Ginko biloba, therefore, it follows that confection of modified carpenter has an unpleasant mouthfeel in the form of tingling sensation or astringency characteristic of said group of botanicals.

Thus, the rejection of step b) over Carpenter in view of Rayment meets the limitation recited in lines 6-7 of claim 1 and similar recitation in claims 28 and 55.

Regarding step (c) of claims **1, 28 and 55 and claims 56-57**, Carpenter teaches of partially hydrogenated vegetable oils or saturated fats in an amount of less than 5% or more than 3% based on the type of confection (Carpenter, column 9, lines 1-6) where saturated fat may be cocoa butter or butter as recited in claims 1, 28, 55-57 (see Carpenter, column 6, lines 58-67 and Column 7, lines 1-7) which includes values that overlap applicant's claimed range of from about 0.5% to about 5.0% by weight, as recited in claims 1, 28 and 55. It is noted that the recitation wherein the agent is "an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals" and said amount "being effective to suppress said unpleasant mouthfeel" of said botanical are a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case given that the amount of hydrogenated vegetable

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oils or saturated fats taught by Carpenter falls in the recited range (Column 6, lines 58-67 and Column 7, lines 1-7), it follows that the prior art (i.e., Carpenter as described above) structure is capable of performing the intended use, i.e., an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals and said amount being effective to suppress said unpleasant mouthfeel".

Regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

Further, Regarding the limitation of utilizing partially hydrogenated vegetable oils or saturated fats as unpleasant mouthfeel suppressing agent, Seang teaches that lipids (oils and fats) were known for masking the bitter taste (i.e., unpleasant mouthfeel) (Seang, Page 1, line 28, Page 4, lines 6-15, 35-37; Page 5, lines 5-7; Page 6, lines 5-15). Thus, effect of lipids in masking the unpleasant mouthfeel was known at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the lipids, i.e., partially hydrogenated vegetable oils or saturated fats as disclosed by Carpenter will mask or suppress the unpleasant mouthfeel of a component or ingredient, such as a botanical. One of ordinary skill in the art at the time the invention was made would have reasonable expectation that fats and oils as disclosed by carpenter will function in a manner that is similar to the lipids and the partially hydrogenated vegetable oils or saturated fats in the instantly claimed invention and suppress the unpleasant mouthfeel which is in the form of a tingling sensation or astringency.

Regarding type of fats, Carpenter teaches of fat derived from vegetable sources including corn oil, soybean oil, peanut oil, palm oil, sunflower oil, and also teaches of hydrogenated vegetable oils (Column 7, lines 1-6). Carpenter also teaches that the saturated fat may be cocoa butter or butter (Column 6, line 67 to Column 7, line 2) as

recited in claims 1, 28, 56-58. However the reference is silent about the specific examples of partially hydrogenated vegetable oils or fats being selected from cottonseed, soybean, peanut, palm, sunflower or corn oil as recited in **claims 4 and 31**. However, addition of partially hydrogenated form of fats was well known in the art, for example, Seang teaches of partially hydrogenated vegetable oils including cottonseed oil (Page 6, lines 1-15) for the purpose of masking the effect of an unpleasant flavor. Thus, addition of partially hydrogenated and saturated fats to mask the flavor or suppress the mouthfeel of botanicals was known in the art at the time of the invention and it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Carpenter in view of Seang and utilize a partially hydrogenated vegetable oil, such as cottonseed oil, in the confection composition. One of ordinary skill would have been motivated to do so at least for the purpose of substituting one type of saturated fat for another type of saturated fat in the instantly claimed invention based on the availability of the fat.

Further it is noted that saturated fats, such as, cocoa butter or butter, and hydrogenated vegetable oil (, i.e., an oil that has been hydrogenated to convert the unsaturated into saturated fats), such as cottonseed oil will act similarly in a hard confection as disclosed by Carpenter, i.e., cocoa butter and butter of Carpenter are functional equivalents of partially hydrogenated cottonseed oil of Seang. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one art recognized functional equivalent (i.e. partially hydrogenated cottonseed oil, saturated fat disclosed by Seang) for another (i.e. cocoa butter or butter, saturated fats taught by Carpenter) in the confection as disclosed by Carpenter, depending on which saturated fat was more easily available and affordable at the time the invention was made. The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07).

Regarding claims **6, 7, 33 and 34**, Carpenter teaches that the saturated fat or partially hydrogenated vegetable oil may be present at greater than about 3% and less than 5%

(Column 9, lines 1-6), which falls in the recited ranges of 0.5% to 3.5% (for claims 6 and 33) or 0.75% to 3.0% (for claims 7 and 34). Regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

Regarding claims **8, 9, 35 and 36**, Carpenter teaches that the ratio of the saturated fat or partially hydrogenated vegetable oil to the botanical is from about 1:1 to 3:1 (Col. 7, lines 40-45), which includes ratio values that falls in the recited range of ratios of 1/1 to about 1/0.01 (for claims 8 and 35) and from 1.0/0.6 to 1.0/0.15 (for claims 9 and 36). Regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

New **claims 58 and 59** recite an added limitation that "wherein the hard boiled candy composition contains no botanical other than Echinacea, Siberian ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. John's wort, Valerian and Ephedra and combinations thereof" Regarding the limitations of new claims 58 and 59, Carpenter as modified for claims 1 and 55, teaches substantially the same product with botanical selected from applicant's claimed list. Regarding the limitation that hard boiled candy contain no botanical other than listed botanicals or combinations thereof, applicant's attention is invited to Raymont where it is disclosed that a confection (page 3, lines 30-31), which comprises at least one botanical, wherein the botanical may be Echinacea and Ginko Biloba (page 3, lines 19-20). Thus, confections including hard confections with botanicals, wherein there are no botanicals other than Echinacea and Ginko biloba (both recited in the list of claims 58-59), were known in the art at the time of the invention. Therefore, it would have been obvious to



one of ordinary skill in the art at the time of the invention to modify Carpenter to include only botanicals such as, Echinacea or Ginko Biloba or both to the confection as claimed. One of ordinary skill would have been motivated to modify Carpenter and include recited botanicals as least for the purpose of deriving known benefits of botanicals, such as, Echinacea for the stimulation of immune system (see Raymont, page 5, lines 20-25) and Ginko Biloba for the stimulation of circulatory system (see Raymont, page 5, lines 20-25). One of ordinary skill in the art would have been motivated to limit the variety of botanicals used to only those that are essential to the product, thus reducing the number of ingredients which results in reduced complexity of the product which in turn can impact product cost.

### ***Response to Arguments***

Applicant's arguments submitted 1/31/2011 regarding the rejection have been fully considered but are not persuasive.

I) Applicants argue that "all elements of the compositions of independent claims 1 and 55 are not disclosed or suggested by the cited combination of references." (remarks, page 10, last 2 lines). Applicants seem to arrive at this conclusion based on the reason that "Carpenter does not disclose, or even suggest, a hard boiled candy composition comprising at least one botanical selected from the group consisting of Echinacea, ... Ephedra, and combinations thereof, each having an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals; or an amount of from about 0.5% to about 5.0% by weight ... of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, ... consisting of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals as required in independent claims 1 and 55." (Remarks, page 9, lines 1-11) and similar reasons against Raymont and Seang provided on (page 9, para 3 and page 10, para 4). This line of argument is not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case

- i) Carpenter teaches a hard boiled candy composition comprised of a mixture of at least one sugar (Carpenter, column 6, lines 20-28) and at least one carbohydrate bulking agent (Carpenter, column 6, lines 33-35) which is kept in an amorphous or glassy condition (Carpenter, column 2, lines 55-61) as claimed.
- ii) Regarding step (c) of claims **1, 28 and 55 and claims 56-57**, Carpenter teaches of partially hydrogenated vegetable oils or saturated fats in an amount of less than 5% or more than 3% based on the type of confection (Carpenter, column 9, lines 1-6) where saturated fat may be cocoa butter or butter as recited in claims 1, 28, 55-57 (see Carpenter, column 6, lines 58-67 and Column 7, lines 1-7) which includes values that overlap applicant's claimed range of from about 0.5% to about 5.0% by weight, as recited in claims 1, 28 and 55. It is noted that the recitation wherein the agent is "an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals" and said amount "being effective to suppress said unpleasant mouthfeel" of said botanical are a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case given that the amount of hydrogenated vegetable oils or saturated fats taught by Carpenter overlaps the recited range (Column 6, lines 58-67 and Column 7, lines 1-7), it follows that the prior art (i.e., Carpenter as modified above) structure is capable of performing the intended use, i.e., fat in Carpenter is capable of suppressing an unpleasant mouthfeel or "tingling sensation or astringency characteristic of said group of botanicals and said amount being effective to suppress said unpleasant mouthfeel" as recited in the rejected claims.

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iii) Regarding step (b) of independent claims 1, 28 and 55, Carpenter discloses at least one botanical (e.g., cocoa powder, see Column 2, lines 65-67) having an unpleasant mouthfeel; however, Carpenter is silent as to the botanical being one from the list provided in amended claim 1, 28 and 55, i.e., botanical is selected from the group consisting of "Echinacea, Siberian Ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof". However, compositions comprising botanicals as claimed were known and available at the time of the invention, and Raymont is relied upon to show the conventionality of botanicals, such as Echinacea and Ginko biloba in a confection, such as a lozenge (page 3, lines 30-31 and page 3, lines 19-20). Further, Raymont also discloses that botanicals like Echinacea were well known for their beneficial characteristics, like stimulatory effect on immune system (Raymont, page 5, lines 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Carpenter and include botanicals such as, Echinacea and/or Ginko Biloba. One of ordinary skill would have been motivated to modify Carpenter and make a hard confection comprising one or more botanicals as claimed, at least for the purpose of deriving known benefits of botanicals, such as, Echinacea for the stimulation of immune system (see Raymont, page 5, lines 20-25) and Ginko Biloba for the stimulation of circulatory system (see Raymont, page 5, lines 20-25).

Regarding the limitation of "unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals" is associated with botanicals "Echinacea, Siberian ginseng, Ginko Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. John's wort, Valerian and Ephedra and combinations thereof" (claims **1, 28 and 55**) is understood to mean that if any or a combination of above listed botanicals are present in a confection or food product, said botanicals will inherently contribute an unpleasant mouthfeel in the form of a tingling sensation or astringency characteristic of said group of botanicals to the confection or food product. Furthermore, it is noted that the limitation of "having an unpleasant mouthfeel in the form of tingling sensation or astringency characteristic of said group of botanicals" (See

e.g., lines 8-9 of claim 1, also part of independent claims 28 and 55) is inherent if any one of the claimed group of botanicals is present. Since, Carpenter as modified above (rejection of step b) teaches Echinacea and Ginko biloba, therefore, it follows that confection of modified Carpenter has an unpleasant mouthfeel in the form of tingling sensation or astringency characteristic of said group of botanicals. Thus, the rejection of step b) over Carpenter in view of Raymont meets the limitation recited in lines 6-7 of claim 1 and similar limitation in claims 28 and 55.

iv) Seang is relied upon to provide evidence that utilizing partially hydrogenated vegetable oils or saturated fats reduce or suppress the unpleasant mouthfeel in a composition. Seang teaches that coating with lipids (oils and fats) were known for masking the unpalatable taste (i.e., unpleasant mouthfeel) of drug compositions (Seang, Page 1, line 28, Page 4, lines 6-15, 35-37; Page 5, lines 5-7; Page 6, lines 5-15). Thus, effect of lipids in masking the unpalatable or unpleasant mouthfeel was known at the time of the invention. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the lipids, i.e., partially hydrogenated vegetable oils or saturated fats as disclosed by Carpenter will mask or suppress the unpleasant mouthfeel of a component or ingredient, such as a botanical. One of ordinary skill in the art at the time the invention was made would have reasonable expectation that fats and oils as disclosed by Carpenter will function in a manner that is similar to the lipids and the partially hydrogenated vegetable oils or saturated fats in the instantly claimed invention and suppress the unpleasant mouthfeel which is in the form of a tingling sensation or astringency.

Further, regarding the perception of unpleasant taste in a solid composition as claimed as compared to the liquid or suspension as taught by Seang, it is noted that the function of masking a taste is similar whether the taste to be masked is that of a solid or liquid. In order for an individual to perceive a taste, a part of the material to be tasted has to reach the taste receptors of the tongue. This typically happens by dissolution of the material to be tasted in saliva (see ref how does taste work obtained from <http://www.ratbehavior.org/RatTaste.htm>). Thus, the mechanism of experience taste is similar whether the material to be tasted is in a solid or a liquid form; and hence addition

of fat that masks a taste functions in a similar manner, whether the fat is added to mask the taste of a solid or a liquid material.

Thus, Carpenter, Raymont and Seang in combination teach all elements of independent claims 1, 28 and 55.

II) Applicant's argue against the rationale of rejection (Page 11). In response to applicant's argument that "Examiner's rationale for combining references is technically faulty" (Remarks, page 11, lines 1-2), applicants are reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case

- Carpenter teaches that confections as claimed with a botanical that causes unpleasant mouthfeel (cocoa) and containing fat or lipid of claimed type and in the claimed range were known at the time of the invention, i.e., an amount of from about 0.5 % to about 5.0% by weight consisting of one or more partially hydrogenated vegetable oils or saturated fats, is taught by Carpenter. As recited in independent claims "said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals.", i.e., Carpenter teaches of unpleasant mouthfeel suppressing agent in an effective amount as claimed.
- Raymont discloses that confections, such as lozenges, containing one or more of claimed botanicals were also known in the art at the time of the invention. Since the confection with claimed botanicals were known their unpleasant mouthfeel in the form of a tingling sensation was also known.
- Further, Seang is relied to show that one of skill had the knowledge that fats and lipids including partially hydrogenated vegetable oils including cottonseed oil

(Page 6, lines 1-15) for the purpose of masking the effect of an unpleasant flavor were known to mask the unpalatable taste of composition, such as drugs. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the lipids, i.e., partially hydrogenated vegetable oils or saturated fats as disclosed by Carpenter will act as masking agents to suppress the unpleasant mouthfeel of a component or ingredient in the hard candy, such as the unpleasant mouthfeel of a botanical. One of ordinary skill in the art at the time the invention was made would have reasonable expectation that fats and oils as disclosed by Carpenter will function in a manner that is similar to the lipids and the partially hydrogenated vegetable oils or saturated fats in the instantly claimed invention and suppress the unpleasant mouthfeel which is in the form of a tingling sensation or astringency.

III) Applicants argue against references individually to show why they are not applicable

i) Applicant's argument against Carpenter is that Carpenter adds cocoa powder and uses lipid to mix the cocoa powder " Carpenter discloses that use of air-jet-milled cocoa powders impart characteristic chocolate flavor to the hard candy without the "sandpaper texture". (col. 9, lines 20-23) Carpenter further discloses that oil, ...richness to the final product and improves the texture thereof. (col. 6, lines 58-65)" (Remarks, page 8, lines 17-22). This argument is not persuasive as applicant is attacking references individually where the rejection is based on combination of references. In response to applicant's argument that Carpenters' addition of oil, facilitates mixing the air-jet milled cocoa powder and the amorphous candy mass by facilitating dispersion of the air-jet milled cocoa powder and adds perceived richness to the final product and improves the texture thereof, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Further, applicant's independent claims recite "an amount of from about 0.5 % to about 5.0% by weight of

said hard boiled candy composition of an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals, said unpleasant mouthfeel suppressing agent consisting of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress said unpleasant mouthfeel of said group of botanicals.”, which requires one or more partially hydrogenated vegetable oils or saturated fats in an amount from about 0.5 % to about 5.0% by weight of the candy composition, which is taught by Carpenter,(Carpenter, column 9, lines 1-6) where saturated fat may be cocoa butter or butter as recited in claims 1, 28, 55-57 (see Carpenter, column 6, lines 58-67 and Column 7, lines 1-7). Further, it is noted that the recitation wherein the agent is “an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals” and said amount “being effective to suppress said unpleasant mouthfeel” of said botanical are a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case given that the amount of hydrogenated vegetable oils or saturated fats taught by Carpenter overlaps the recited range (Column 6, lines 58-67 and Column 7, lines 1-7), it follows that the prior art (i.e., Carpenter as modified above) structure is capable of performing the intended use, i.e., fat in Carpenter is capable of suppressing an unpleasant mouthfeel or “tingling sensation or astringency characteristic of said group of botanicals and said amount being effective to suppress said unpleasant mouthfeel” as recited in the rejected claims.

b) Applicant's also argue that Carpenter does not teach the claimed method (claim 28) but teaches “that the oil is added to the air-jet milled cocoa powder prior to mixing with the amorphous candy mass in order to facilitate mixing of the cocoa powder with the amorphous candy mass”. This argument is not persuasive because First of all Carpenter teaches addition of lipid and clearly states “ oil...is preferred in the chocolate flavored hard candy confection of the present invention. It is preferred that

the oil is either a dairy-based oil or a vegetable oil. The oil, when present, facilitates the mixing of the air-jet milled cocoa powder and the amorphous candy mass by facilitating the dispersion of the air-jet milled cocoa powder" wherein addition of fat to confectionery mass and cocoa is disclosed as claimed. Applicant's quote of Carpenter Column 7, is directed to a preferred embodiment but general disclosure of Carpenter does not exclude addition of fat in the manner as claimed.

Secondly, applicant's claim 28 is directed to "providing ...a mixture of one sugar and carbohydrate bulking agent which is kept in an amorphous and glassy condition and a botanical...said group of botanicals and ...botanicals". Thus, the claim recites a mixture of A (at least one sugar) and B (at least one carbohydrate), which is kept in an amorphous glassy condition, and C(botanical), wherein the claim does not require C to be mixed in with A and B. Claim 28 does not recites a mixture of A, B and C, which would indicate a mixture of three components. Thus, claim 28 is being interpreted as mixture of A and B, and a botanical where the botanical is not mixed (which is met by Carpenter), whereas applicant's argument is based on the assumption that claim recites a mixture of A, B and C, which would indicate a mixture of three components.

ii) Applicants argue against Raymont that Raymont "does not provide any explicit examples of the composition in any formulation other than a tablet. (pp. 7-8)" (Remarks, page 9, para 2, lines 7-9). This argument is not persuasive as Raymont is relied upon in an obviousness rejection in a combination of references where primary reference to Carpenter teaches the claimed confection type. Further, Raymont clearly discloses that his composition may be formulated as tablets, capsules, lozenges, emulsions, solutions, and suspensions (p. 3, lines 30-31).

iii) Applicant's state that Seang is not applicable because "Seang is directed to dosage forms that are liquid dispersions of a particular selection of bitter drugs (cimetidine, ranitidine, ibuprofen, acetaminophen, or erythromycin) and methods of preparing such dispersions." (Remarks, page 11, para 1). Applicant's argument is not persuasive. In response to applicant's argument that Seang is nonanalogous art, it has



been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Seang is pertinent as it is trying to solve the particular problem of taste masking an unpleasant or unpalatable mouthfeel causing composition, i.e., a drug, wherein the unpleasant mouthfeel is masked (Page 4, lines 35-37) by mixing a lipid with an unpleasant mouthfeel causing agent (Page 2, lines 30-32).

iv) Applicant's also argue that "examiner has provided no evidentiary support for the proposition that a method of taste-masking a particular selection of drugs in a liquid dispersion format would have motivated an artisan to include an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of a botanical selected from Echinacea, Siberian Ginseng, Ginkgo Biloba, Kola Nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. Johns Wort, Valerian and Ephedra, and combinations thereof," (remarks, page 10, para 2). This argument is also not persuasive because, Carpenter in view of Raymont teach the elements of the claimed invention including the type of confection, unpleasant tasting botanical and claimed type of lipid in the claimed range, as recited in the independent claims 1, 28 and 55. Thus, adding lipid in the Carpenter's disclosed range to a hard candy composition with one or more botanicals as taught by Raymont would achieve the claimed suppression in unpleasant mouthfeel. Seang is merely relied upon to show evidence that applicant's claimed effect of adding lipids or fats to reduce the unpleasantness was known as Seang uses fats for a similar effect of taste masking of an unpleasant tasting composition which is achieved by mixing of fat with unpleasant tasting composition. see response to argument I for further details.

IV) Applicants claim unexpected results and cite examples, where unexpectedly superior reduction in the unpleasant tingling sensation (Remarks , page 11, last para and page 12, para 1). This argument is not persuasive because:

i) The combination of references (Carpenter, Raymont and Seang) teach the lipid component in the claimed range of the applicant, as discussed above in response to arguments I). It is noted that the recitation wherein the agent is “an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals” and said amount “being effective to suppress said unpleasant mouthfeel” of said botanical are a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case given that the amount of hydrogenated vegetable oils or saturated fats taught by Carpenter falls in the recited range (Column 6, lines 58-67 and Column 7, lines 1-7), it follows that the prior art (i.e., Carpenter as described above) structure is capable of performing the intended use. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success that lipid as taught by Carpenter will function as an unpleasant mouthfeel suppressing agent for suppressing the tingling sensation or astringency characteristic of said group of botanicals and said amount being effective to suppress said unpleasant mouthfeel.

ii) Further applicant's argue “superior reduction in the unpleasant tingling sensation”, but do not provide a standard against which the superior reduction of unpleasant mouthfeel is being measured.

iii) Furthermore, applicants argue “superior reduction in the unpleasant tingling sensation”, but the claim recites “suppressing” the “unpleasant mouthfeel” but does not recite “superior reduction” in the unpleasant mouthfeel as argued. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., superior reduction in the unpleasant tingling sensation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

V) Applicant's argument regarding the process claim have also been considered and responded in the response to arguments I and III above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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